No. 10–762

IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

RESPONDENTS BAYER AG & BAYER CORP.'S BRIEF IN OPPOSITION

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
CHRISTOPHER S. PERRY
MARK R. LENTZ
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

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FRED H. BARTLIT, JR.
Counsel of Record
PETER B. BENSINGER, JR.
MICHAEL J. VALAIK
PAUL J. SKIERMONT
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 West Hubbard St.
Chicago, IL 60654
(312) 494-4400
fred.bartlit@bartlit-beck.com

COUNSEL FOR RESPONDENTS BAYER AG & BAYER CORP.

QUESTION PRESENTED

Whether settlement of patent litigation that excludes no more competition than the exclusionary scope of the patent gives rise to antitrust liability where (1) patent infringement was conceded, and (2) the antitrust plaintiff does not allege that the patent was invalid, unenforceable, procured by fraud, or asserted in sham litigation.

CORPORATE DISCLOSURE STATEMENT

Bayer Corporation is a wholly-owned subsidiary of Bayer AG. There is no publicly-held company that owns more than 10% of Bayer AG.

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INTRODUCTION

The law is that a patent owner can exclude infringing competition within the patent's exclusionary effect. Here, Bayer settled patent litigation in which infringement was conceded and the settlement excluded only competition within the patent's exclusionary effect.

The Second Circuit held below that Bayer had no antitrust liability because the settlement was within the scope of the patent and the Petitioners did not contend that Bayer procured its patent by fraud or asserted it in sham litigation. Nor could they. After the settlement, the validity of Bayer's patent was upheld by the Patent Office on reexamination, in three district court challenges, and on appeals to the Federal Circuit.

The ruling below does not conflict with the decisions of any other court of appeals. As the Solicitor General has advised the Court several times, there is no circuit split on the question presented, and cases like this one that arose under the prior regulatory regime that Congress amended in 2003 do not present good vehicles for review. This Court denied certiorari in all of those cases, and nothing has occurred to alter the analysis. On the contrary, the Federal Circuit has since affirmed the same order of the same district court on an appeal by a different group of plaintiffs, and this Court again denied certiorari, without seeking the views of the United States. Making no new arguments, the present Petition misreads the same caselaw and misstates the same facts. The Court should deny certiorari, just as it did before.

COUNTERSTATEMENT OF THE CASE

Statutory And Regulatory Background

1. The Sherman Act and the Patent Act each promote competition, but through different means. The Sherman Act protects competition, not competitors, by prohibiting monopolization and unreasonable restraints on trade. *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 906 (2007). The Patent Act promotes competition by rewarding the innovation that leads to new and better products. It does so through the patent's grant of "the right to exclude others." U.S. Const., art. I, § 8, cl. 8; 35 U.S.C. § 154. When patentees pursue that right through litigation, this Court has long embraced the policy favoring settlement of patent suits. *E.g.*, *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), the Court sought to achieve "a suitable accommodation … between the differing policies of the patent and antitrust laws" when the patentee's conduct is within the scope of the subject patent. *Id.* at 179 (Harlan, J., concurring). *Walker Process* held that proof of fraud in securing a patent "would be sufficient to strip [the patentee] of its exemption from the antitrust laws." *Id.* at 177. Beyond such intentional misconduct, however, the patentee's "good faith would furnish *a complete defense*" to antitrust claims. *Id.* (emphasis added).

2. a. The Drug Price Competition and Patent Term Restoration Act, or the "Hatch-Waxman Act," addresses the interaction between patent protection

and generic drugs. Pub. L. No. 98-417, 98 Stat. 1585 (1984). Under Hatch-Waxman, a prospective generic drug manufacturer filing an Abbreviated New Drug Application ("ANDA") must demonstrate that the "active ingredient of the new drug is the same as that of the listed [or innovator's] drug." 21 U.S.C. § 355(j)(2)(A)(ii)(I). This enables the generic to avoid the time and expense of conducting its own clinical trials. The statute also gave the first generic ANDA filer 180 days of market exclusivity before another generic could enter the market. *Id.* § 355(j)(5)(B)(iv).

To protect the rights of patentees, the statute requires an ANDA filer seeking FDA approval before expiration of any patent claiming the listed drug to certify that the patent "is invalid or … will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"). The ANDA filer must then notify the patent holder of its Paragraph IV Certification. *Id.* § 355(j)(5)(B)(iii).

Under Hatch-Waxman, the ANDA filing is an "artificial" act of patent infringement even though the filer has made no infringing sales. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); 35 U.S.C. § 271(e)(2)(A). If the innovator drug manufacturer sues for infringement within 45 days of receipt of notice of the ANDA filing, then the FDA is stayed for 30 months from approving the ANDA. *Id.*

Hatch-Waxman thereby changed the risks of ordinary patent litigation. In traditional litigation, the accused infringer risks paying damages for its infringing sales. In ANDA litigation, however, the generic challenger has no risk of paying damages, as it can challenge the patent without entering the market. Thus, its exposure is limited to litigation

costs. Yet, the innovator can have billions at risk. As a result, settlements with the innovator paying the generic challenger — so-called "reverse payment" settlements — are "a natural by-product of the Hatch-Waxman process." *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("*Cipro II*").

Although Hatch-Waxman changed the risk allocation, it did not otherwise alter patent litigation. Nothing in Hatch-Waxman was "intended to modify existing patent law with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed." H.R. Rep. No. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661.

b. Congress amended Hatch-Waxman in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Congress changed the provisions governing the first-filer's 180-day exclusivity period (21 U.S.C. § 355(j)(5)(B)(iv)(I)) and required that parties settling ANDA litigation submit their settlement agreements to the FTC (*id.* § 355(j)(5)(D)(i)(V)).

Since 2003, legislation has been introduced to change the antitrust framework applicable to reverse-payment settlements. *See*, *e.g.*, S. 27, 112th Cong. (2011); S. 369, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009). In the last Congress, the House passed such bills twice, as did two Senate Committees, but none was finally enacted.

Background Of The Case

1. Bayer owns U.S. Patent No. 4,670,444 ("'444" or the "Cipro Patent"). Pet. App. 13a. Claim 12 of the Cipro Patent covers the ciprofloxacin molecule, which is the drug's active ingredient. Because a generic drug must have the same active ingredient as the innovator, all formulations of generic Cipro would infringe Bayer's patent. *See id.* at 39a-40a.

The Cipro Patent expired on December 9, 2003. *Id.* at 13a. The FDA granted Bayer an additional six months of "pediatric exclusivity." *Id.* n.1. After Bayer's patent and pediatric exclusivity ended on June 9, 2004, generic Cipro became widely available. *See* FDA, Drugs: First-Time Generics – June 2004, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/UCM063712.htm (last visited Feb. 3, 2011).

2. In 1991, Barr Laboratories, Inc. ("Barr") notified Bayer that it had filed an ANDA seeking to market generic Cipro before '444's expiration. Pet. App. 13a. There was "no dispute that Barr's product would have infringed Bayer's [compound] patent," so Barr alleged that '444 was invalid and unenforceable. *Id.* 40a.

Bayer sued Barr for patent infringement in the Southern District of New York. *Id.* at 15a-16a. Thereafter, The Rugby Group, Inc. ("Rugby"), a subsidiary of Hoechst Marion Roussel, Inc. ("HMR"), entered into a "Litigation Funding Agreement" with Barr. *Id.* at 41a. (HMR later sold Rugby to Respondent Watson Pharmaceuticals, Inc.)

Shortly before trial, Bayer and Barr settled. *Id.* at 16a-17a. Barr agreed to a Consent Judgment affirming '444's validity and to amend its ANDA such that it could market generic Cipro only after '444 expired. In exchange, Bayer agreed to license a competing ciprofloxacin product at least six months before Bayer's patent expired. Bayer also had the option to grant a longer license or to make settlement payments over a six-year period. Bayer chose to make payments, which ultimately totaled $398.1 million, or 6.5% of Bayer's U.S. gross sales of oral Cipro tablets for the payment period. Supp. App. 2a.

After settling, Bayer submitted '444 to the U.S. Patent and Trademark Office ("PTO") for reexamination. *See* Pet. App. 42a-43a. The PTO confirmed the validity of claim 12 covering the ciprofloxacin molecule. *Id.*

Also after the settlement, four generic drug manufacturers filed ANDAs seeking to market generic Cipro (Ranbaxy, Mylan, Schein, and Carlsbad). *Id.* at 17a n.9. Bayer sued each for infringement. The Ranbaxy challenge was dismissed as moot after Ranbaxy withdrew its ANDA. Bayer defeated Schein and Mylan on summary judgment, and the Federal Circuit affirmed. *Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001), *aff'd*, 301 F.3d 1306 (Fed. Cir. 2002). Bayer won a bench trial against Carlsbad, which did not appeal.

3. a. Starting in 2000, direct and indirect purchasers of Cipro filed antitrust challenges to the settlement. Pet. App. 17a. The MDL Panel consolidated those cases before the late Judge David Trager in the Eastern District of New York. *See In re*

Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740, 745 (E.D.N.Y. 2001) ("*Cipro I*").

In 2003, Judge Trager denied all Plaintiffs' motions for partial summary judgment, rejecting their argument that the settlement was per se unlawful. *Cipro II*, 261 F. Supp. 2d 188. The Indirect Purchaser Plaintiffs later amended their complaint to add a state-law *Walker Process* claim based on fraud before the PTO. Pet. App. 37a. The Direct Purchaser Plaintiffs — Petitioners here — did not amend their complaints.

In 2005, Judge Trager granted judgment for Defendants on all claims. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) ("*Cipro III*"), Pet. App. 36a. He held, "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." Pet. App. 79a (citations omitted). Because "plaintiffs ha[d] not shown that the [Settlement] Agreements had anti-competitive effects beyond the scope of the '444 Patent," their claims failed. *Id.* at 92a-93a. Judge Trager also dismissed the state-law *Walker Process* claim as preempted by federal patent law and noted that no fraud on the PTO had occurred. *Id.* at 104a n.28, 108a.

All Plaintiffs appealed to the Second Circuit. The Second Circuit transferred the Indirect Purchasers' appeal to the Federal Circuit due to their *Walker Process* claim (*see id.* at 20a n.10), but retained the Direct Purchasers' appeals.

b. Shortly after Plaintiffs appealed, the Second Circuit decided a different Hatch-Waxman case, in which it adopted Judge Trager's legal analysis and cited his *Cipro* opinions seventeen times. *Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.)*, 466 F.3d 187 (2d Cir. 2006). *Tamoxifen* found that the alleged "reverse payment" was not suspect, but rather consistent with "the patent holder's incentive to settle the lawsuit … even when it is relatively confident of the validity of its patent." *Id.* at 210. *Tamoxifen* then adopted its governing rule directly from Judge Trager: "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Id.* at 213 (quoting *Cipro III*, 363 F. Supp. 2d at 535, Pet. App. 79a).

The Second Circuit denied rehearing en banc, and this Court denied certiorari. 551 U.S. 1144 (2007).

c. In 2008, a unanimous Federal Circuit panel affirmed Judge Trager's ruling in the appeal transferred from the Second Circuit. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) ("*Cipro IV*"). The Court reaffirmed the rule that Judge Trager and other circuits applied:

> [I]n cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of

> reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent."

Id. at 1336 (citing *Walker Process*, 382 U.S. at 175-77).

The Federal Circuit found that Judge Trager's approach was consistent with other circuits' precedents and that, absent fraud or sham litigation, "the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." *Id.* at 1334-36. The Court also found that the settlement did not create a "bottleneck" delaying other generics or precluding their market entry. *Id.* at 1338.

The Federal Circuit also agreed with Judge Trager that federal law preempted the state-law *Walker Process* claim. In so holding, the Court found that Bayer had not committed fraud on the PTO: "[T]he district court determined, *and we agree*, that no fraud occurred." *Id.* at 1341 (emphasis added).

The Federal Circuit denied rehearing en banc, and this Court denied certiorari. 129 S. Ct. 2828 (2009).

d. On April 29, 2010, in this appeal, the Second Circuit likewise affirmed Judge Trager's ruling. *See*

Pet. App. 24a-25a. Under *Tamoxifen*, there could be no "injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Id.* at 25a.

Nonetheless, the panel "invite[d] plaintiffs-appellants to petition for in banc rehearing." *Id.* at 35a. This invitation was based in part on a mistaken reading of *Tamoxifen* and the pre-amendment, 2003 version of the Hatch-Waxman Act, which governs this case. Bayer moved to correct the opinion.

The panel granted Bayer's motion in part and corrected its opinion on June 17, 2010. *See Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010), Pet. App. 9a. Afterward, the full Second Circuit denied the petition for rehearing en banc without calling for a response from Respondents. Pet. App. 2a. The panel's presiding judge, Rosemary Pooler, filed a lone dissent from denial of rehearing en banc. *Id.* at 3a. This Petition followed.

REASONS FOR DENYING THE PETITION

Nothing has changed to merit review since this Court denied certiorari to review the Federal Circuit's affirmance of the same district court ruling at issue. There is no split in the circuits, the rule applied below flows directly from this Court's precedents, and this case presents a poor vehicle for resolving the question presented.

I. THERE IS NO CONFLICT OF AUTHORITY

The Second, Eleventh, and Federal Circuits all agree that, absent fraud on the PTO or sham litigation, patent settlements within the exclusionary scope of the patent are lawful.

Petitioners conjure a supposed "three way" circuit split by invoking the same cases that the Indirect Purchasers advanced when this Court declined to review the Federal Circuit's decision in this case. In fact, every case that Petitioners claim is in conflict with the ruling below issued before the Solicitor General last advised the Court that no conflict exists.

A. The Second Circuit Ruling Does Not Conflict With Any Appellate Decision

The circuits consistently have applied the "scope of the patent" rule to Hatch-Waxman settlements. Indeed, all of the circuits to have addressed reverse payment settlements — even the Sixth Circuit, on which Petitioners principally rely — have cited with approval Judge Trager's reasoning in this case. *See Tamoxifen*, 466 F.3d at 213; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 n.13 (6th Cir. 2003).

Here, the Second Circuit applied the controlling rule that there could be no "injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." Pet. App. 25a (quoting *Tamoxifen*, 466 F.3d at 213) (further citation omitted). The settlement could not have "exceeded the scope of the Cipro patent," since "a generic version of Cipro would necessarily infringe Bayer's patent." *Id.* at 26a. Here, moreover, "Plaintiffs do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud." Pet. App. 26a.

The Second Circuit's rulings in this case and in *Tamoxifen* are wholly consistent with the Federal Circuit's *Cipro* decision as well. The Federal Circuit held that "[t]he essence of the [antitrust] inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." *Cipro IV*, 544 F.3d at 1336. Where the settlement is within the patent's scope, and there is no "evidence of fraud on the PTO or sham litigation," there is no antitrust violation. *Id.* at 1335. As the court explained, "[t]his analysis has been adopted by the Second and Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent." *Id.* at 1336 (citing *Walker Process*, 382 U.S. at 175-77).

In reaching their decisions, the Second and Federal Circuits also relied upon the Eleventh Circuit's decisions in *Schering-Plough* and *Valley Drug*. *See* Pet. App. 24a (citing *Schering-Plough*, 402 F.3d at 1076); *Cipro IV*, 544 F.3d at 1333-37. In those decisions, the Eleventh Circuit held that the "exclusionary effect of the patent" is the starting point for the antitrust analysis. *Valley Drug*, 344 F.3d at 1306 (internal quotation marks omitted); *Schering-Plough*, 402 F.3d at 1068. Applying that standard, the Eleventh Circuit held in *Schering-Plough* that, because there was no allegation of sham litigation or fraud on the PTO, "the proper analysis now turns to whether … the challenged agreements restrict competition beyond the exclusionary effects of the … patent." 402 F.3d at 1068. [1]

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[1] The Eleventh Circuit in *Schering-Plough*, like the Second Circuit in *Tamoxifen* and the Federal Circuit in *Cipro IV*, cited

Since this Court denied certiorari in *Cipro IV*, three more district courts have acknowledged the consensus among the circuits and adopted the scope of the patent rule. *See In re K-Dur Antitrust Litig.*, No. 01-1652, 2010 WL 1172995 (D.N.J. Mar. 25, 2010) (Order adopting Special Master's Amended Report and Recommendations, *available at* 2009 WL 508869, at *27 (D.N.J. Feb. 6, 2009)) (Third Circuit Judge Greenaway, sitting by designation); *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010); *King Drug Co. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010) (applying rule of *Tamoxifen* and *Cipro IV*, but denying a motion to dismiss because complaints alleged that the settlements exceeded the patent's scope).

B. Petitioners' Circuit Split Argument Ignores The Language Of The Cases

1. *The Sixth and D.C. Circuits.* Contrary to Petitioners' assertion, neither the Sixth Circuit nor the District of Columbia Circuit "have adopted the 'patent strength' standard," which supposedly bases liability "on the patent litigants' own view of the likely outcome of the [patent] litigation" being settled. *See* Pet. 14-18. Ignoring the analysis of these cases, Petitioners staple together partial quotations, none of which articulates Petitioners' purported standard, nor uses the term "patent strength" to describe it.

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with approval Judge Posner's analysis in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003), which also applied the "objectively baseless" test. *Schering-Plough*, 402 F.3d at 1074-75; *Tamoxifen,* 466 F.3d at 208-10; *Cipro IV*, 544 F.3d at 1337.

The Sixth Circuit's decision in *Cardizem* and the D.C. Circuit's decision in *Andrx Pharmaceuticals, Inc. v. Biovail*, *Corp.*, 256 F.3d 799 (D.C. Cir. 2001), analyzed the same settlement arising from litigation about the drug Cardizem. Every court to discuss the facts has observed that the settlement at issue imposed restraints *beyond* the exclusionary scope of the patent.

In the Cardizem settlement, the generic manufacturer agreed not to market even "non-infringing formulations" and to block other generic entrants through manipulating the 180-day exclusivity period. *See Cardizem*, 332 F.3d at 902; *Andrx*, 256 F.3d at 804. In contrast, the Cipro Patent covers all formulations of generic Cipro and Barr agreed to amend its ANDA, removing any obstacle to other generics. Thus, the Sixth and D.C. Circuit decisions are fully consistent with the decision below and other circuit decisions. *See, e.g.*, *Tamoxifen*, 466 F.3d at 214; *Valley-Drug*, 344 F.3d at 1311 n.26.

Andrx, moreover, is entirely inapposite. The D.C. Circuit did not even address the legality of reverse payments, much less hold them to be per se illegal. Rather, the court considered whether a dismissal for lack of antitrust injury was appropriate. The court found that it was, but should not have been with prejudice. *Andrx,* 256 F.3d at 801. The passage Petitioners quote (Pet. 17) was in the section of the *Andrx* opinion discussing "Antitrust Injury" (256 F.3d at 812) and the court was accepting for purposes of that discussion the "alleg[ation] that Andrx entered into an anticompetitive *agreement* with HMRI in order to exclude others." *Id.* at 813. In addressing "but for" injury, the court simply rejected defendants'

argument that Andrx would not have actually entered the market, even though it planned to do so.[2]

Unlike the D.C. Circuit in *Andrx,* the Sixth Circuit in *Cardizem* did rule on the legality of the patent settlement before it, but not using the analytical framework Petitioners urge. Thus, when Petitioners quote the sentence in *Cardizem* stating that a patentee may not "bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market" (Pet. 16), they exclude a key footnote in that very sentence citing Judge Trager's analysis in *Cipro* with approval. *Cardizem*, 332 F.3d at 908 n.13. In the footnote Petitioners omit, the Sixth Circuit adopted Judge Trager's analysis of why *Cardizem* was distinguishable from *Cipro* — because the Cardizem settlement covered non-infringing products, and thus exceeded the scope of the patent:

> As the court in *In re Ciprofloxacin* observed, ["][w]hen the Cardizem [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained

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[2] No court has read *Andrx* as containing a holding concerning the legality of reverse payments. The Cipro Indirect Purchasers who sought certiorari from the Federal Circuit did not cite or discuss *Andrx* in the section of their Petition arguing that there is a circuit split. Petition for Certiorari at 19-24, *Cipro IV*, 129 S. Ct. 2828 (2009) (No. 08-1194), 2009 WL 797579. Nor did Judge Pooler cite *Andrx* in dissenting from the denial of en banc review below and asserting that there was a "conflict among the Courts of Appeals." Pet. App. 8a. Not even the Sixth Circuit in *Cardizem* — decided a full two years after *Andrx* — so much as mentioned it. *See Cardizem*, 332 F.3d at 899-915.

> Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation[.] Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.["]

332 F.3d at 908 n.13 (first, fifth, and sixth alterations added).

When this Court sought the views of the Solicitor General regarding certiorari in *Cardizem,* he explained that the Sixth Circuit did not adopt a per se rule against payments. Rather, the agreement there prohibited the "marketing not only of allegedly infringing products but also of non-infringing or potentially non-infringing products that were not at issue in the patent litigation." Brief for United States as Amicus Curiae at 7, 13-15, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S 939 (2004) (No. 03-779), 2004 WL 1562075 ("Cardizem Br."). As support, the Solicitor General relied expressly on the *Cardizem* footnote citing Judge Trager's opinion. *Id.* at 14-15.

Since then, the Court has twice more sought the Solicitor General's views, and twice more been told that *Cardizem* presents no conflict. Brief for United States as Amicus Curiae at 16 n.7, *Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830), 2007 WL 1511527 ("Tamoxifen Br.") (distinguishing *Cardizem* and citing Cardizem Br. at 16-17); Brief for the United States as Amicus Curiae at 16-17, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441 ("Schering-Plough Br.").

Every circuit that has discussed the Cardizem settlement has recognized that it went beyond the exclusionary effect of the patent. The Federal Circuit noted that "the [Cardizem] agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug," and thus, "clearly had anticompetitive effects outside the exclusion zone of the patent." *Cipro IV*, 544 F.3d at 1335. The Second Circuit also distinguished *Cardizem*, emphasizing that under the Cardizem agreement, "the generic manufacturer would not market non-infringing products." *Tamoxifen*, 466 F.3d at 214. The Eleventh Circuit agreed that certain provisions of the Cardizem agreements "seem to exceed the potential exclusionary power of the patent." *Valley Drug*, 344 F.3d at 1311 n.26.

2. *The Eleventh Circuit.* Petitioners contend that the Eleventh Circuit has adopted a different standard calling for "an ex-post judicial determination of the patent issues" (Pet. 18), in which the merits of the patent claim would "be relitigated as part of the antitrust case" (*id.* at 13). The cases are to the contrary.

In *Valley Drug*, the Eleventh Circuit faulted the district court for "fail[ing] to consider the exclusionary power of Abbott's patent in its antitrust analysis." 344 F.3d at 1306. Quoting *Cipro II* with approval, *Valley Drug* asserted that "the exclusionary effect of the patent must be considered *before* making any determination as to whether the alleged restraint is *per se* illegal." *Id.* (quoting *Cipro II*, 261 F. Supp. 2d at 249) (emphasis added).

With respect to settlements within the patent's exclusionary effect, the Eleventh Circuit expressly

rejected the argument that the merits of the patent claim should be "relitigated": "[E]xposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives." 344 F.3d at 1308. The court noted the potential for a "sham" exception (*id.* at 1308-09 & n.21), but found that it would not apply because "appellees have demonstrated nothing more than subsequent invalidity." *Id.* at 1309.

Valley Drug involved an "interim settlement" that did not resolve the ongoing patent case, which continued and later found the patent invalid. 344 F.3d at 1300-01. Thus, when *Valley Drug* issued, there was nothing to "relitigate." The patent had been held invalid, and the patent owner was estopped from contesting invalidity. This is why the FTC subsequently told this Court that any "suggestion that a post hoc inquiry into the patent merits would satisfy the [Eleventh Circuit] is *disingenuous* because *Valley Drug* squarely precludes a conclusion of liability on that basis." Reply Br. for Petitioner at 2, *Schering-Plough*, 548 U.S. 919 (No. 05-273), 2005 WL 2652617 (citation omitted and emphasis added).

Petitioners' argument here is based exclusively on statements made in Section "D" of the *Valley Drug* opinion, where the court considered the allegation that the settlement agreement went *beyond* the scope of the patent. 344 F.3d at 1311. In doing so, the court emphasized that "[t]o the extent these or other effects of the Agreements are *within* the scope of the exclusionary potential of the patent, such effects are *not* subject to *per se* antitrust condemnation." *Id.* at

1311 (emphases added). The court added that "[a]pplication of rule of reason analysis is similarly inappropriate, as the anticompetitive effects of exclusion cannot be seriously debated." *Id.* n.27.

But the rule of reason analysis *could* apply to settlement provisions that went beyond the scope of the patent. It was in that respect only that *Valley Drug* suggested that the district court consider "the likelihood of [the innovator's] obtaining" similar protections via "the preliminary injunction and stay mechanisms." *Id.* at 1312. That dicta cannot change the court's express holding with respect to conduct within the patent's scope.

Nor did *Schering-Plough* change the law of the Eleventh Circuit. 402 F.3d at 1065 ("We are bound by our decision in *Valley Drug*"). After noting that there were no allegations of invalidity or sham litigation, *Schering-Plough* stated that "the proper analysis now turns to whether … the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent." *Id.* at 1068 (citing *Valley Drug*, 344 F.3d at 1306).

Petitioner's argument with respect to *Schering-Plough* is based on a single phrase in the opinion's conclusion, stating that a legal ban on settlement payments would ignore "the need to evaluate the strength of the patent." 402 F.3d at 1076. If taken as an endorsement of "relitigating" the patent merits in an antitrust case, the statement would conflict not only with *Valley Drug,* but with the analysis of *Schering-Plough* itself.

Earlier in *Schering-Plough*, the Eleventh Circuit expressly equated the patent's exclusionary effect

with the scope of the patent claims. *Id.* at 1073 ("The '743 patent claims a 'controlled release microencapsulated potassium chloride tablet.' The language in the Schering-Upsher agreement covers the identical reach of the '743 patent."). The Court also stated on the same page as the "strength" reference that "the agreements fell well within the protections of the '743 patent, and were therefore not illegal." *Id.* at 1076. Judge Trager properly rejected Petitioners' misreading of those words, concluding that "this admonition [in *Schering-Plough*] is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity." *Cipro III*, 363 F. Supp. 2d at 539, Pet. App. 89a.

When this Court sought the views of the United States regarding certiorari in *Schering-Plough*, the Solicitor General considered the decisions in the Sixth and Eleventh Circuits, as well as the Second Circuit's intervening decision in *Tamoxifen*. Schering-Plough Br. at 16-20. The United States concluded that "there is no circuit split justifying this Court's review." *Id.* at 16.[3]

In sum, the circuit cases are in harmony, uniformly citing Judge Trager's *Cipro* analysis with approval. Hence, this Court has denied certiorari in five prior

[3] In its *Tamoxifen* brief, the United States identified no conflict, but stated that *Schering-Plough* "arguably" could be read not to "foreclose the possibility that a party challenging a patent settlement could rely on an ex ante view of the strength of the infringement claim." *Tamoxifen* Br. 16. As we have shown, there is no case support for that "possibility." A district court in the Eleventh Circuit recently rejected the same reading of *Schering-Plough*. *In re Androgel*, 687 F. Supp. 2d at 1377-79.

cases presenting the same issue (including the Federal Circuit's affirmance of the district court opinion at issue here).[4] These denials underscore the absence of any circuit conflict or reason to grant certiorari now. *See Miroyan v. United States*, 439 U.S. 1338, 1338-39 (1978) (Rehnquist, Circuit Justice) ("[U]nless applicants can demonstrate a conflict among the Courts of Appeals of which this Court was unaware at the time of the previous denials of certiorari, or which has developed since then, applicants' petition for certiorari will not [be granted] ….").

II. FUNDAMENTAL ANTITRUST PRINCIPLES SUPPORT THE RULE ADOPTED BELOW

A. The "Scope of The Patent" Rule Is Correct

As the Court has recognized, "the essence of a patent grant is the *right to exclude others* from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) (emphasis added); *accord Bement v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902) ("The very object of [the patent laws] is monopoly."); 35 U.S.C. § 154. Thus, when patents are involved, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) (citing *Bement*, 186 U.S. at 91).

Because antitrust law recognizes the patentee's right to exclude, "the public [is] not entitled to profit

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[4] *Cipro IV*, 129 S. Ct. 2828 (2009); *Tamoxifen*, 551 U.S. 1144 (2007); *Schering-Plough*, 548 U.S. 919 (2006); *Valley Drug*, 543 U.S. 939 (2004); *Cardizem*, 543 U.S. 939 (2004).

by competition among infringers." *See, e.g.*, *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907). The antitrust plaintiff therefore bears the burden of showing that the "excluded" competition for which it seeks relief was lawful competition. *See, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (no antitrust liability for conspiring to preclude the importation of illegal drugs); *Access Telecom, Inc. v. MCI Telecommc'ns Corp.*, 197 F.3d 694, 712 (5th Cir. 1999). As Judge Posner has explained, where a plaintiff makes no attempt to satisfy that burden, it cannot show harm to competition "since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Asahi Glass*, 289 F. Supp. 2d at 994.

In this case, Barr admitted infringement, and Petitioners do not allege that the Cipro Patent was invalid, much less that Bayer's suit against Barr was "objectively baseless." Hence, application of the scope of the patent rule is straight-forward: agreements within the exclusionary scope of the patent do not violate the antitrust laws. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [antitrust] inquiry."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in the grant of the patent"); *Studiengesellschaft*, 670 F.2d at 1128 ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by

the patent, and is otherwise legal."); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws.").

That Bayer made payments to Barr to settle Hatch-Waxman litigation does not change the "right to exclude" analysis. Under the statute, an ANDA filer infringes simply by filing its Paragraph IV Certification. *See* 35 U.S.C. § 271(e)(2)(A). Because the ANDA filer has not yet made any sales subjecting it to infringement damages, the generic challenger bears no risk in the ensuing litigation beyond litigation costs. *See Cipro II*, 261 F. Supp. 2d at 252. The innovator, however, faces the same invalidity challenge as it faces in any infringement suit in which the entire patent is at risk. *See Tamoxifen*, 466 F.3d at 207. Thus, as the Federal Circuit concluded, "a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed." *Cipro IV*, 544 F.3d at 1333 n.11. Under Hatch-Waxman the innovator has everything to lose and the generic challenger has everything to gain. Settlement payments from the innovator to the generic challenger are therefore "a natural by-product of the Hatch-Waxman process." *Cipro II*, 261 F. Supp. 2d at 252; *accord Schering-Plough*, 402 F.3d at 1074-76; *Valley Drug*, 344 F.3d at 1310.

The courts below correctly applied these principles to this patent settlement, holding that such settlements incur antitrust liability only if their

effects exceed the patent's exclusionary scope *or* if there was fraud in the patent's procurement *or* if the infringement suit was objectively baseless. Because the settlement was within the scope of Bayer's patent, it excluded no more competition than the patent itself lawfully excluded.

B. The Ruling Below Does Not Conflict With This Court's Precedents

1. The "scope of the patent" rule that Judge Trager and the Second Circuit adopted is consistent with this Court's jurisprudence. Indeed, this Court's decision in *Walker Process*, 382 U.S. 172, shows the rule's propriety. *See Valley Drug*, 344 F.3d at 1307 (describing *Walker Process* as "[t]he only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced.").

In *Walker Process,* defendant raised an antitrust counterclaim alleging that the patentee "obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office." 382 U.S. at 177. The United States as amicus curiae argued that an infringement defendant could bring such a claim where the patent had been procured by actual fraud. Brief for the United States as Amicus Curiae at 7, *Walker Process*, 382 U.S. 172 (No. 13), 1965 WL 130091. The government stressed, however, that "[t]he case is entirely different from one in which a patent secured in good faith subsequently is held invalid, for there the intent to secure a monopoly is consonant with the purpose of the patent laws." *Id.*

This Court agreed that an antitrust claim would lie where the patentee committed fraud on the PTO.

Walker Process, 382 U.S. at 177. The Court admonished, however, that "[b]y the same token, [the patentee's] good faith would furnish a complete defense." *Id.* In his oft-cited concurrence, Justice Harlan emphasized that antitrust liability does not attach merely on the basis of patent *invalidity*:

> [T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed available to reach § 2 monopolies carried on under a nonfraudulently procured patent.

Id. at 180 (Harlan, J., concurring).

Judge Trager and the Federal Circuit expressly relied on *Walker Process* in their *Cipro* opinions. *Cipro III,* 363 F. Supp. 2d at 530, Pet. App. 68a-69a; *Cipro IV,* 544 F.3d at 1336. Both the scope of the patent rule and its "objectively baseless" exception flow from this Court's insistence that "good faith" reliance on patent rights furnishes a "complete defense" to antitrust liability. *Walker Process*, 382 U.S. at 177. To base an antitrust claim against parties acting within the scope of a patent on anything less than a sham patent claim would

conflict with the express exclusion of private claims "show[ing] no more than invalidity of the patent." *Id.* at 179 (Harlan, J., concurring). Judge Trager correctly perceived that Petitioners' liability theories "would overstep the bright-line rule adopted by the Supreme Court in *Walker Process*, first elaborated upon by Justice Harlan in his concurrence and relied upon by the patent bar for the past forty years." *Cipro III,* 363 F. Supp. 2d at 530, Pet. App. 68a-69a.

2. Although the scope of the patent rule flows from *Walker Process*, Petitioners nonetheless claim that the rule conflicts with general statements in several of "this Court's patent cases." *See* Pet. 24. Petitioners' patent cases, however, are inapposite, as explained below.

Petitioners contend that the decision below conflicts with this Court's "repeated[] emphasi[s] that judicial testing of patent validity is essential" to secure the public interest, citing, *inter alia*, *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). *See* Pet. 24-26. But *Lear* only considered whether a licensee could ever bring a challenge to the validity of the licensor's patent, and did not address whether the licensee could then settle that suit. If judicial testing of patent validity was essential, then all patent settlements would be unlawful. That is not the law: "Where there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement rather than litigation, is not precluded by the [Sherman] Act." *Standard Oil*, 283 U.S. at 171.[5]

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[5] Likewise, *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), concerned only a federal court's jurisdiction to hear a

Petitioners also contend that the scope of the patent standard ignores this Court's distinction between the substantive right to exclude and the "limited, qualified remedies" available to enforce that right. Pet. 27 (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392 (2006)). *eBay*, however, "h[e]ld only that the decision whether to grant or deny injunctive relief … must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases." 547 U.S. at 394. The Court did not purport to limit the traditional remedy of infringement damages and said nothing about the ability to settle patent cases.

C. Petitioners' And Amici's "Policy" Arguments Are Unsupported and Unpersuasive

Petitioners urge the Court to disregard its own precedent and settled circuit law on grounds of "public policy." But the Petitioners and their amici invoke a strangely one-sided "policy" — one that assumes that consumers benefit only when a patent holder loses in court; one that assumes that consumers always prefer the short-term benefits of lower generic prices to the long-term benefits of newly discovered, life-saving drugs. As the current General Counsel of the FTC has noted, however, that argument "ignores the first principle that enforcing valid patents makes a major contribution to consumer welfare by providing the incentive for innovation. We ignore that incentive at our peril." Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements:*

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licensee's declaratory judgment challenge to the licensed patent, not whether a declaratory judgment action could be settled.

The Need for Context and Fidelity to First Principles, 15 Fed. Cir. B.J. 617, 618 (2006).

In any event, Petitioners make many assertions of "fact" without record support, relying instead on public pronouncements from interested parties. For example, the opening paragraph of the Petition states that innovator drug companies "are today routinely — 15 to 20 agreements every year — paying generic drug manufacturers … to delay entering the market," and that "these agreements are annually costing consumers and taxpayers billions of dollars." Pet 2. Neither statement is defensible.

First, in asserting that so-called reverse-payment settlements are ongoing and increasing, Petitioners rely not on record evidence, but on FTC annual reports of settlements filed pursuant to the 2003 amendments to Hatch-Waxman. The FTC analysis of those reports is based on an Orwellian redefinition of the term "payments" to include settlements with no cash payments at all, such as settlements with exclusive licenses.[6] In fact, since settlements have been reported to the FTC in 2004, only *five* included cash payments to the generic, and all were small amounts for "litigation" expenses.[7]

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[6] *See* Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2008 ("FY 2008 Report") 1 n.2 & 2, *available at* http://www.ftc.gov/os/2010/01/100113-mpdim2003rpt.pdf.

[7] *See* FY 2008 Report at 4 (one settlement); Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug Improvement Act of 2003, Summary of Agreements Filed in FY 2007 ("FY 2007 Report") 4, *available at*

Second, Petitioners' assertions regarding the social costs of settlements is based on a recent FTC "Study" whose title reflects its bias: Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study (2010) *available at* www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. Commentators have shown that the study is flawed and its central conclusion on consumer benefits "is not reliable."[8] Among other things, it compares the entry dates for different settlements without controlling for salient differences, including "the average patent life remaining" at the time of settlement.[9] Even with its flaws, the study concedes that the consumer "loss" it derives could fall from $3.5 to "$0.6 billion" (*i.e.*, over

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http://www.ftc.gov/os/2008/05/mmaact.pdf (one settlement); Federal Trade Commission, Agreements Filed With FTC Under the Medicare Prescription Drug Improvement Act of 2003, Summary of Agreements Filed in FY 2006 ("FY 2006 Report") at 4, *available at* http://www.ftc.gov/reports/mmact/MMAreport2006.pdf (three settlements). The reports for FY 2004 and FY 2005 reflect no cash payments. The FTC has not issued an FY 2009 report.

[8] Bret Dickey et al., *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on 'Reverse Payment' Settlements* at 2 (2010), *available at* http://newsroom.law360.com/articlefiles/186893-Analysis.pdf; *See also, e.g.,* Anjan Chatterji & Xiang Yu, *Impact of Reverse Exclusionary Settlements on Consumer Welfare: A Law and Economic Analysis*, 23 Antitrust Health Care Chronicle, July 2010, at 2, 5 (with necessary adjustments, "the [alleged] benefits in the FTC Findings are reduced to a minimum.").

[9] Dickey et al., *supra* note 8, at 3 ("Such differences would render invalid the comparison of entry delay between the two types of settlements.").

82%) if some of its (undisclosed) "assumptions," were "varied." *Id.* at 10.

Based on another FTC study, several amici recite the incorrect assertion that, "between 1992 to 2000, … the patent owner lost 73% of the cases" filed under Hatch-Waxman. Brief Amici Curiae of 86 Professors ("Professors Br.") at 10 (discussing Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002) ("FTC 2002 Study"), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf). Yet, the study refutes that claim because it shows a success rate for first-filers in all cases of just 29%. FTC 2002 Study at 14-16 (22 victories in 75 challenges). To produce a 73% "success" rate, the FTC had to reduce the number of total drug products considered, eliminating cases still pending, cases that settled, cases in which the generic withdrew its ANDA, and — critically here — cases in which the same drug patent was litigated more than once. *Id.* at 19. Thus, Bayer's three separate Cipro victories counted as only one win for a patent holder. Subsequent studies have found that the actual generic success rate is less than 50%.[10]

The flaws in Petitioners' extra-record materials show why appellate courts focus on evidence actually presented and proven in court. Whatever their merit,

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[10] Adam Greene & D. Dewey Steadman, *Pharmaceuticals, Analyzing Litigation Success Rates,* RBC Capital Markets 1 (2010) (overall generic success rate of 48% was significantly lower in courts and before judges who saw the greatest volume of cases), *available at* http://amlawdaily.typepad.com/pharmareport.pdf; *see also* Gregory Glass, *Why Settle?*, UPDATE, Sept.-Oct. 2005, at 17-18 (generic challenger prevailed in 35% of cases brought).

Petitioners' policy arguments should be addressed to Congress, not to this Court.

III. THIS CASE IS A POOR VEHICLE TO RESOLVE THE QUESTION PRESENTED

1. a. This settlement arose under the regulatory regime in place before Congress substantially amended the Hatch-Waxman Act in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. As the Solicitor General noted in *Tamoxifen* (a pre-2003 settlement case), Congress "altered the regulatory dynamic" under which the settlement here is to be evaluated when it amended the Hatch-Waxman Act in 2003. Tamoxifen Br. at 19.

The 2003 amendments counsel against review of issues arising from a small set of settlements in an outdated regulatory context. *See* Eugene Gressman et al., Supreme Court Practice 247 (9th ed. 2007) ("If the statute upon which the controversy rests has expired or been amended in a manner that will prevent the problem from arising in the future, certiorari may be denied ….").

The 2003 amendments to Hatch-Waxman included, among other things, a new provision governing the first generic filer's right to 180 days of "exclusivity" before other generics may enter. Petitioners claimed that the exclusivity provisions created a "bottleneck" by preventing subsequent challenges to the patent after a settlement. Petitioners' argument was based on the *prior* statute's 180-day exclusivity provision, not the current provisions.

Petitioners argued in the district court that the pre-2003 statute's treatment of a "bottleneck" was central to the analysis of reverse payments. Petitioners' theory was that later entry by other generics could not remove the alleged harm of settlement payments because "[f]uture challenges" were deterred by "Defendants' manipulation of the 180-day exclusivity." Mem. of Direct Purchaser Pls.' in Opp'n to Defs.' Mots. for Summ. J., *Cipro* MDL (July 9, 2004) (Supp. App. 11a). Petitioners' co-plaintiffs also argued that the pre-2003 "bottleneck" made a reverse payment settlement "far more damaging to competition than the garden variety agreement not to compete." Indirect Purchaser Class Pls.' Mem. of Law in Opp'n to All Defs.' Mots. to Dismiss, *Cipro* MDL (May 22, 2002) (Supp. App. 6a). The commentators on whom Petitioners rely emphasize that the 180-day exclusivity period "make[s] [Hatch-Waxman] patent settlements *fundamentally different* from other patent infringement settlements."[11]

But in this case, the undisputed facts belie any "bottleneck" claim because multiple generic challenges followed the settlement. *See* Pet. App. 17a n.9.

The point for certiorari analysis is that the current statute fundamentally undermines Petitioners' reliance on the "bottleneck" theory in all cases. The

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[11] Herbert Hovenkamp et al., IP and Antitrust § 7.4, at 7-34 (2004) (emphasis added); David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 331 (2000) ("Hatch-Waxman Act [exclusivity] provides one critical feature that makes a world of difference ….").

2003 amendments introduced the term "first applicant" for purposes of exclusivity, changed the triggering mechanism, ensured that any entry under a settlement license would trigger the 180 days, and provided a series of mechanisms by which exclusivity could be forfeited. *See* 21 U.S.C. § 355(j)(5)(B)(iv), (D). In the words of a draftsperson, the 2003 amendments "ensure that the 180-day exclusivity period … cannot be used as a bottleneck to prevent additional generic competition."[12]

The Solicitor General has advised this Court on multiple occasions that the 2003 amendments to the Hatch-Waxman Act make cases decided under the prior statute poor vehicles for certiorari: "To the extent the Court is inclined to address the validity of that type of settlement in particular, it may be preferable to do so in a case that arises under the current regulatory regime." Tamoxifen Br. at 20; *see also* Cardizem Br. at 18-19. The advice remains sound. If the Court were to grant certiorari here, it would resolve questions relating to the prior statute that are of no prospective application. Such a decision could lead to confusion under the different language of the current regime.

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[12] 149 Cong. Rec. 31200 (2003) (Remarks of Sen. Schumer); *see also* 149 Cong. Rec. 31783 (2003) (Remarks of Sen. Kennedy) ("The Hatch-Waxman provisions in this bill are intended to prevent parking of the exclusivity."); *see generally* Natalie M. Derzko, *The Impact Of Recent Reforms Of The Hatch-Waxman Scheme On Orange Book Strategic Behavior And Pharmaceutical Innovation*, 45 IDEA 165, 245 (2005) ("In particular, the new 180-day exclusivity provision should prevent anticompetitive settlement agreements from being entered into.").

b. Congress is in the midst of considering legislation that could moot the issues in this case going forward. In the last Congress, Senator Kohl's Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009), was voted out of the Senate Judiciary Committee. The bill declared presumptively illegal "any agreement resolving or settling a patent infringement claim" in which the "ANDA filer receives anything of value." *Id.* § 3. Congressman Rush introduced the similar Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009), which the House twice included in larger bills, only to be dropped in the reconciliation process. *See, e.g.*, Supplemental Appropriations Act of 2010, H.R. 4899, 111th Cong. (2010). Senator Kohl has already introduced nearly identical legislation in the current Congress. Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011).

2. This case is also a poor vehicle because Petitioners have not set forth the legal rule that they wish the Court to adopt. Nor have they made any attempt to show that the outcome of this case would change under a legal rule different from that applied below. While Petitioners criticize the current law, they offer no alternative rule, much less any defense of that rule. The academic amici concede that they "differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements." Professors Br. at 5.

This Court does not issue advisory opinions. *See Preiser v. Newkirk*, 422 U.S. 395, 401 (1975). Nor is the Court required to guess at the proper rule, nor to apply for the first time an analysis that no court may

have considered. *See The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959) ("Resolution here of the [issue presented] can await a day when the issue is posed less abstractly.").

3. Finally, the Petition presents a poor test case in view of the Cipro Patent's track record. The validity of Bayer's patent has been vindicated before the PTO on reexamination, in three district court challenges to judgment, and at the Federal Circuit. *See Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). In fact, on the appeal of the Indirect Purchasers in this case, the Federal Circuit agreed that no fraud on the PTO had occurred. *Cipro IV*, 544 F.3d at 1341. As Judge Trager stated, "there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit." *Cipro III*, 363 F. Supp. 2d at 530 n.14, Pet. App. 67a n.14. Petitioners make no argument that any test based on the "strength" or possible invalidity of the patent would change the result in this case. *See* Pet. 14-15, 21-22. Thus, Judge Trager concluded, "a *post hoc* assessment of the validity of the ciprofloxacin patent would likely do plaintiffs little good." *Cipro III*, 363 F. Supp. 2d at 530, Pet. App. 70a.

CONCLUSION

The Court should deny the Petition as it did in this case on certiorari to the Federal Circuit.

Respectfully submitted,

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
CHRISTOPHER S. PERRY
MARK R. LENTZ
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

February 4, 2011

FRED H. BARTLIT, JR.
Counsel of Record
PETER B. BENSINGER, JR.
MICHAEL J. VALAIK
PAUL J. SKIERMONT
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard St.
Suite 300
Chicago, IL 60654
(312) 494-4400
fred.bartlit@bartlit-beck.com

Counsel for Respondents Bayer AG & Bayer Corp.

SUPPLEMENTAL APPENDIX*

* The materials excerpted in this Supplemental Appendix were originally filed under seal in the district court pursuant to a stipulated protective order. However, by subsequent agreement, these excerpts are no longer under seal, and the excerpts do not refer to any document that remains under seal.

APPENDIX A

FILED UNDER SEAL

This document contains reference to highly confidential and confidential material subject to Protective Order

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION	)	**Master File No. 1:00-MD-1383**
This Document Relates to:	)	**Hon. David G. Trager, U.S.D.J.**
	)	**Hon. Steven M. Gold, U.S.M.J.**
ALL ACTIONS	)	

AFFIDAVIT OF RAYMOND RASIMAS

County of New Haven	)	
	)	ss: West Haven, CT
State of Connecticut	)	

Raymond Rasimas, being sworn, deposes and says:

1. My name is Raymond Rasimas. I attest to the following facts based on personal knowledge.

2. My current title is Senior Financial Specialist. I am primarily responsible for providing financial

analysis to management; ensuring and reporting Bayer's compliance with its 3rd party contracts; and interfacing with all functional areas of Bayer in support of the collection of financial data.

3. In January 1997, Bayer paid to the Barr Escrow Account a total of $49.1 million. The payment represented 6.2% of Bayer's 1997 U.S. gross sales of oral Cipro tablets ($787.1 million). From 1997 through the end of 2003 when Bayer ceased payments, Bayer's settlement payments totaled $398.1 million, representing 6.5% of Bayer's U.S. gross sales of oral Cipro tablets for the period ($6.1 billion).

I declare under penalty of perjury that the foregoing statements and information are true and correct.

/s/ Raymond J. Rasimas
Raymond Rasimas

Sworn to before me
this 26th day of May 2004

/s/ Elaine Porter
Notary Public

Elaine Porter
Notary Public
My Commission Expires June 30, 2006

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION	Master File No. 1:00-MDL-1383 Hon. David G. Trager, USDJ Hon. Steven M. Gold, USMJ
THIS DOCUMENT RELATES TO: ALL INDIRECT PURCHASER CLASS CASES	

INDIRECT PURCHASER CLASS PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO ALL DEFENDANTS' MOTIONS TO DISMISS THE INDIRECT PURCHASER CLASS PLAINTIFFS' COMPLAINTS

FILED UNDER SEAL PURSUANT TO STIPULATED PROTECTIVE ORDER GOVERNING CONFIDENTIAL MATERIAL DATED JULY 9, 2001

* * *

A. A Combination Of The Pioneer Drug Patent Holder And The First ANDA(IV) Filer Can Result In An Unreasonable Restraint Of Trade.

Holders of valid patents are liable for antitrust violations when they combine with horizontal competitors to exclude competition, as have Bayer, Barr, HMR and Rugby. *See*, *e.g.*, *Andrx*, 256 F.3d at 812 n.15 ("[E]ven a patent-right holder is not immune from antitrust liability."); *Terazosin I*, 164 F. Supp. 2d at 1354 ("Abbott's efforts to parlay its patents into agreements with its competitors to limit the domestic sale of generic Terazosin hydrochloride drugs is exactly 'the type of commercial activity that has traditionally had its validity determined by the antitrust laws.'") (citations omitted); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir.), *cert. denied*, 122 S. Ct. 350 (2001) ("'Intellectual property rights do not confer a privilege to violate the antitrust laws.'") (citation omitted). In *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963), the Supreme Court held that competitors can violate the antitrust laws when they "pool" their patent rights for exclusionary purposes. *See id.* at 194.

> It is well settled that beyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law, and "it is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of its patent monopoly. By aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act."

> That Act imposes strict limitations on the concerted activities in which patent owners may lawfully engage, and those limitations have been exceeded in this case.

Id. at 196-97 (citations and quote marks omitted); *see also United States v. New Wrinkle, Inc.*, 342 U.S. 371, 379 (1952).

The Exclusivity Period under the Hatch-Waxman Act is analogous to a patent in that it provides government-sanctioned insulation from generic competition for 180 days in order to reward and encourage conduct that is in the public interest. *Andrx*, 256 F.3d at 813 n.15. Just as a valid patent results in a carefully tailored monopoly designed to reward investment and innovation, the Exclusivity Period incentivizes generic companies to develop around and challenge pioneer companies' patents. Patents and the Exclusivity Period are narrowly construed exceptions to the general rule against monopolies and the right to a free and open market. *Andrx*, 256 F.3d at 813 n.15. Under the language of the Hatch-Waxman Act, the FDA has the authority to grant final approval to an ANDA(IV) after the 30-month stay expires, thus enabling the applicant to bring its product to the market despite the pendency of patent litigation. *See Ciprofloxacin*, 166 F. Supp. 2d at 744; Cpt. ¶ 42. Commercial marketing following FDA approval will "trigger" the Exclusivity Period, which will then open the door, 180 days later, to FDA approval for other generic manufacturers to enter the market.

The Hatch-Waxman Act necessarily contemplates that the patent holder and the first ANDA(IV) filer

must be adversaries, with the latter fighting to get its competitive product to the market as soon as possible to reap the benefits of 180 days as the exclusive generic. These rights are so inherently incompatible,[11] the statutory scheme does not contemplate a partnership between these would-be competitors by which the first ANDA(IV) filer withholds its product from the market (thereby keeping all generic competition at bay) in exchange for a share of the monopoly rents from the pioneer manufacturer. *See Andrx*, 256 F.3d at 809 ("[T]he statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period."); *see also Cardizem I*, 105 F. Supp. 2d at 657-58; *Biovail*, 49 F. Supp. 2d at 767-68. As such an agreement precludes new entry by other potential competitors, it is far more damaging to competition than the garden variety agreement not to compete. *See Andrx*, 256 F.3d at 814 ("Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may temporarily possess it."); Balto, 55 Food & Drug L. J. at 332 ("Agreements that restrict new entry therefore are viewed with great concern.").

* * *

[11] It is inconceivable, for example, that the same entity could be both the pioneer patent holder and the first ANDA(IV) filer – *i.e.*, a pharmaceutical company (either directly or through a subsidiary) could not file an ANDA(IV) and challenge the validity of its own patent so as to claim the Exclusivity Period on top of its patent rights.

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

APPENDIX C

CONFIDENTIAL
FILED UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION	Master File No. 100-MDL-1383 Honorable David G. Trager, U.S.D.J. Honorable Steven M. Gold, U.S.M.J.
THIS DOCUMENT RELATES TO: Louisiana Wholesale Drug Co. (No. 00-5191) CVS Meridian, Inc. (No. 00-7951)	

MEMORANDUM OF DIRECT PURCHASER PLAINTIFFS IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT [CORRECTED VERSION]

Bruce E. Gerstein
Barry S. Taus
Steve D. Shadowen
Monica L. Rebuck

CONTAINS CONFIDENTIAL INFORMATION
SUBJECT TO COURT ORDER

Jan Bartelli
Garwin, Bronzaft, Gerstein & Fisher, LLP
1501 Broadway, Suite 1416
New York, NY 10036
(212) 398-0055

Lead Counsel, Direct Purchaser Class Cases

HANGLEY ARONCHICK SEGAL & PUDLIN
30 North Third Street – Suite 700
Harrisburg, PA 17101-1701
(717) 364-1030

Attorneys for Plaintiffs CVS Pharmacy, Inc. and Rite Aid Corporation

Dated: July 9, 2004

* * *

F. Defendants' Proposed Rule Would Result in Significant Consumer Harm.

It is Defendants' proposed rule, not Plaintiffs', that would have far-reaching and dire consequences. Defendants assert that there is no harm to consumers from permitting pioneers to make exclusion payments because consumers can prevail on an antitrust claim in those instances in which the pioneer obtained the patent by fraud or enforced it with no reasonable basis to believe that it was enforceable. (Bayer Br. at 17-19.) Defendants' assertion that antitrust liability should be limited to those circumstances highlights the extreme nature of their proposed rule.

If exclusion payments are allowed, then litigants' economic incentive will be to settle *all* patent disputes that *can* be settled with exclusion payments rather than licenses. (Tab 17 at ¶ 48.) Defendants' own expert agrees with this assessment. (Tab 32 at

88-89.) The result would be the near complete elimination of the vital function that courts play in policing patent validity. (Tab 17 at ¶ 49.)

Defendants try to soften these damning facts by asserting that consumers might be able to state an antitrust claim when the pioneer has entered into a series of exclusion payment settlements. (Bayer Br. at 18) And Defendants attempt to distinguish this case from *Cardizem* and *Terazosin* on the ground that the agreement here allegedly did not have the effect of barring other generic competitors from the market. (Generics Br. at 18-19) Defendants are wrong as a matter of both law and fact.

Antitrust liability attaches to a single act of anticompetitive conduct -- a series of such anticompetitive actions is not required. *See, e.g.*, *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172 (1965) (a single instance of enforcing a fraudulently procured patent can violate Section 2 of the Sherman Act). Moreover, pioneers will in fact make exclusion payments only when it is worthwhile for them to do so -- only when the retained monopoly made possible by the exclusion payment exceeds the amount of the exclusion payment. Thus, the fact that a pioneer has made an exclusion payment to a single potential competitor proves that a payment to that single competitor was all that was necessary to harm consumers. (Tab 17 at ¶ 27, 52).

This case, and the comparison of its facts to those in *Cardizem* and *Terazosin*, illustrate this principle. When Bayer agreed to make the exclusion payments to Barr and HMR/Rugby, no other generic

manufacturer had yet filed an ANDA IV. (Tab 30 at 247.) Under the law as it existed at that time, a subsequently-filing generic challenger would be subject to the automatic 30-month Hatch-Waxman stay. Allowing for time for a second challenger to prepare and file an ANDA IV and then to wait out the 30-month stay, Bayer estimated that the exclusion payment settlement would permit it to be free from *all* generic competition -- not just competition from Barr and HMR/Rugby -- until at least January 2000. (Tab 43H at BCP 4610057.)

Absent the exclusion payment, Bayer estimated that the Federal Circuit would render a decision in the Bayer/Barr litigation by January 1999. (Tab 43H at BCP 4610057.) Barr estimated such a decision would occur by January 1998. (Tab 24 at 227.) Thus, the exclusion payment bought Bayer the absence of *all* generic competition from January 1998 or 1999 to January 2000 -- between 12 to 24 months. (Tab 43H at at BCP 4610057.) That period of exclusion actually exceeds the period involved in *Cardizem* (11 months) and is comparable to that involved in *Terazosin* (16 months). *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 632 (E.D. Mich. 2000); *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F. Supp. 2d 1340, 1347 (S.D. Fla. 2000).

The exclusion payments also bought Bayer a more favorable forum in which to have its patent tested. Bayer's strategy was to settle the Barr challenge and then submit the '444 patent for reexamination at the PTO. Bayer AG's Chairman admitted that the purpose of submitting the patent for reexamination was to *ward off future challenges in the court*

system -- Bayer believed that if it were successful in the reexamination, no other generic manufacturer would challenge the patent in court. (Tab 40 at 69.)

It was in Bayer's economic interest to have the patent's validity tested in the PTO rather than in the courts. (Tab 40 at 68.) A PTO reexamination is an *ex parte* proceeding in which, among other things, the issue of inequitable conduct -- one of the principal arguments raised by Barr -- cannot even be considered. (Tab 17 at ¶ 61.) Bayer was obviously aware of that key fact. (Tab 30 at 166-67.) The PTO is in fact a far more favorable forum for patent holders than are federal courts. Federal courts find 46% of all litigated patents to be invalid. (Tab 17 at ¶ 61 & n.107.) On reexamination the PTO finds only 10% of patents to be invalid. (*Id.*) Bayer in fact concluded that its chances of a favorable decision were substantially greater in the PTO than in the courts. (*Id.* at ¶ 60.)

Finally, Bayer's prediction that its settlement with Barr would ward off future court challenges turned out to be right. Future challenges were not deterred by the PTO ruling, however, but by the extra time that the settlement bought and by the Defendants' manipulation of the 180-day exclusivity.

Before Defendants entered into their unlawful Agreement, another generic manufacturer, Mylan, was preparing to file an ANDA IV. (Tab 38 at 52.) If Barr had not settled the patent litigation and had succeeded in having the '444 patent invalidated, Mylan could have filed its ANDA IV application and had FDA approval to enter the market immediately

upon the expiration of Barr's 180-day exclusivity in or about June 1998. (Tab 16 at 26 n. 53.)

The Defendants' agreement affected the timing of Mylan's filing its ANDA IV application in two ways. First, a generic challenger that is not the first-filer will rationally try to "free-ride" on the legal expenses being incurred by the first-filer. (Tab 17 at ¶ 27.) Once Barr, the first-filer, settled there was some delay while Mylan and the other potential challengers got "up to speed" in the preparation of their patent defenses in earnest. (*Id.*)

Second, at the time of the unlawful agreement, the FDA law was unclear as to whether a first-filer that settled the patent litigation and amended its certification from a Paragraph IV to a Paragraph III would forfeit its 180-day exclusivity. (Tab 17 at p. 15 n.43; *see also Cipro II* at 242.)[28] What *is clear* is that Barr told Bayer during the settlement negotiations that Barr in fact intended to assert its continued right to the 180-day exclusivity. (Tab 42 at 172.) It is also clear that the Defendants collectively maximized Barr's chances of successfully claiming the 180-day exclusivity -- the Defendants expressly provided in the Agreement that, in the event that another generic manufacturer succeeded in invalidating the '444 patent, Barr could *re-amend its*

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[28] In *Cipro II* the Court held, on Plaintiffs' motion for partial summary judgment, that Plaintiffs had failed to establish their claim regarding the 180-day exclusivity *as a matter of law*. In opposition to the Defendants' motion, we are establishing *as a matter of fact* that the purpose and effect of Defendants' settlement agreement was to deter or delay subsequent challenges to the patent.

ANDA certification from a Paragraph III back to a Paragraph IV. (Tab 42A at ¶5.) Obviously, it was in the economic interest of both Barr and Bayer for Barr to succeed in claiming the 180-day exclusivity.

These circumstances in fact delayed Mylan in the filing of its ANDA IV application. Mylan "[did] not see any chance to go ahead with the product with their legal understanding of the Waxman-Hatch exclusivity." (Tab 28.) Mylan finally filed its application in August 1999, immediately after the FDA proposed a new rule that a voluntary change in patent certification from a Paragraph IV to a Paragraph III results in the forfeiture of the 180-day exclusivity. (Tab 38 at 110; 64 Fed. Reg. 42,873 8/8/99.) Mylan has acknowledged that the Defendants' Agreeement "affected the timing of our development." (Tab 38B & 38C at § IV(2); Tab 38 at 96.)

By the time Mylan filed its application in August 1999, there were less than 4 years remaining in the patent term. Mylan could reasonably expect that litigation of an average Hatch-Waxman litigation would take at least 37 months, through a court of appeals decision. FTC, *Generic Drug Entry Prior to Patent Expiration*, iii (July 2002) *available at* http://www.ftc.gov/os/2002/07/genericdrug_study.pdf. (Tab 47).

As acknowledged by Barr's own patent counsel, one of the strongest arguments against the '444 patent was Bayer's inequitable conduct in procuring that patent. (*See* Tab 29 at 170-71.) Faced with a fast-approaching expiration of the '444 patent, Mylan "reluctantly" dropped its inequitable conduct defense.

(Tab 38D at BCP 1941110.) As Mylan recognized, inequitable conduct "is the type of defense [that is] very focused on issues of intent and materiality of these different references, so you're looking at, presumably, a pretty long road to trial." (Tab 38 at 143-45.) Mylan dropped this defense in order to "present a clear issue of law to the district court and to the federal circuit so that the case could come to a resolution" before the patent would expire. (Tab 38 at 133-34.) Thus, as a result of the Defendants' Agreement and their manipulation of the 180-day exclusivity, one of the best arguments for the unenforceability of the '444 patent remains unadjudicated to this day.